DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 6, 2014

Zoll Medical Corporation
Tanmay B. Shukla
Sr. Regulatory Affairs Specialist
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K140502
Trade/Device Name: Zoll E Series ALS
Regulation Number: 21 CFR 870.5300
Regulation Name: DC-Defibrillator (Including Paddles)
Regulatory Class: Class II
Product Code: LDD
Dated: September 8, 2014
Received: September 9, 2014

Dear Tanmay B. Shukla,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K140502

INDICATIONS FOR USE

510(k) Number (if known): K140502

Device Name: ZOLL E Series ALS

Intended Use:

Defibrillator Function

The E Series ALS products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

The E Series ALS products must be prescribed for use by a physician or medical advisor of an emergency response team.

Intended Use — Manual Operation

Use of the E Series ALS products in the Manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In Manual mode, the E Series ALS unit may also be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardias (VT) by using the R-wave of the patient's ECG as a timing reference. A qualified physician must decide when synchronized cardioversion is appropriate.

Intended Use — CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Intended Use — Pacemaker

This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

• Resuscitation from standstill or bradycardia of any etiology

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

• As a standby when standstill or bradycardia might be expected
Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

• Suppression of tachycardia
Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Monitor

Intended-Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO2), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), End Tidal CO2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

ECG monitoring is performed by connecting the patient to the unit via the 3 or 5 lead patient cable, MFE Pads, or through the paddles.

SpO2 monitoring is indicated for detecting arterial oxygen saturation of blood and pulse rate for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpCO monitoring is indicated for detecting carbon monoxide concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpMet monitoring is indicated for detecting oxidized hemoglobin concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO2 monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO2) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction or other cardiac arrhythmias.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A.

978-421-9655
978-421-0025 Main Fax

510(k) Summary:

Applicant's Name and Address:	ZOLL Medical Corporation 269 Mill Road Chelmsford, MA 01824
Application Correspondent:	Tanmay Shukla 978-421-9171
Date Summary Prepared:	September 8, 2014
Classification:	Class II
Device Name	ZOLL E Series ALS
Product Code	Low-Energy – Defibrillators (LDD) Cardiopulmonary Resuscitation Aid (LIX) Cardiac Monitors – including Cardiotachometer and Rate Alarms (DRT) External Transcutaneous Cardiac Non-Invasive Pacemaker (DRO) Noninvasive Blood Pressure Measurement System (DXN) Blood Pressure Computer (DSK) Carbon Dioxide Gas Analyzer (CCK) Oximeter (DQA)
Predicate Devices	ZOLL E Series (K111594 and K092598)

Description:

The predicate ZOLL E Series External Defibrillator/Monitor reviewed and cleared by the FDA (K111594 and K092598) is intended for use by qualified medical personnel who are trained and authorized to respond to medical emergencies, to facilitate the ability to monitor and assess the physiological characteristics of the indicated patients in a critical care environment. It combines the function of a manual defibrillator, noninvasive transcutaneous pacer, ECG monitor, pulse oximeter, end tidal CO2 monitor, 12-Lead EGG monitor, non-invasive blood pressure monitor and CPR performance monitor along with data printing and recording capabilities. Functions are offered as options, and functions can be configured during manufacturing to meet the needs of a particular application.

Through a manufacturing configuration option that is already available in the device's software and currently offered for distribution (reviewed and cleared by FDA under K111594), the ECG rhythm analysis (advisory) option can be disabled during the manufacturing of the device. This creates a manual-only/ non-AED configuration of the device which is marketed as E Series ALS and intended to be used by ACLS qualified personnel. On the hardware side, the front panel that is offered with this configuration does not include the analyze button that is used to initiate ECG rhythm analysis.

Following from the discussion above, E Series ALS is covered under our previously cleared 510(k) submission K111594. This submission is simply intended to seek a stand-alone Class II clearance for E Series ALS, per regulation number 870.5300 for Low-Energy – Defibrillator (LDD), which does not include the Automated External Defibrillators (Non-Wearable) product code (MKJ).

Indications for Use:

Defibrillator Function

The E Series ALS products contain a DC defibrillator capable of delivering up to 200 joules of energy. It may be used in synchronized mode to perform synchronized cardioversion by using the R-wave of the patient's ECG as a timing reference. The unit uses paddles or disposable, pre-gelled, MFE Pads for defibrillation.

The E Series ALS products must be prescribed for use by a physician or medical advisor of an emergency response team.

Intended Use — Manual Operation

Use of the E Series ALS products in the Manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by these three conditions:

- Unconsciousness
- Absence of breathing, and
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In Manual mode, the E Series ALS unit may also be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardias (VT) by using the R-wave of the patient's ECG as a timing reference. A qualified physician must decide when synchronized cardioversion is appropriate.

Intended Use — CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a minimum compression depth of at least 1.5 (3.8 cm) or 2.0 inches (5.0 cm), depending on the configuration, for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

Intended Use — Pacemaker

This product may be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

Note: This device must not be connected to internal pacemaker electrodes.

The purposes of pacing include:

• Resuscitation from standstill or bradycardia of any etiology
Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes- Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

• As a standby when standstill or bradycardia might be expected
Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

• Suppression of tachycardia
Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lbs / 15kg or less using special ZOLL pediatric MFE Pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Monitor

Intended-Use Multi-parameter Monitoring

This product may be used for monitoring various patient vital signs, including: electrocardiogram (ECG), Pulse Oximetry (SpO2), Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), End Tidal CO2, 12-Lead ECG, and Non-Invasive Blood Pressure (NIBP).

ECG monitoring is performed by connecting the patient to the unit via the 3 or 5 lead patient cable, MFE Pads, or through the paddles.

SpO2 monitoring is indicated for detecting arterial oxygen saturation of blood and pulse rate for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpCO monitoring is indicated for detecting carbon monoxide concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

SpMet monitoring is indicated for detecting oxidized hemoglobin concentration in arterial blood for adult, pediatric and neonatal patients who are well or poorly perfusing, during both no motion and patient motion conditions.

EtCO2 monitoring is indicated for the continuous measurement of end tidal carbon dioxide (EtCO2) and respiration rate for adult, pediatric and neonatal patients.

12 Lead ECG analysis is indicated for the diagnosis and treatment of adult and pediatric patients with acute myocardial infarction or other cardiac arrhythmias.

NIBP monitoring is indicated for the measurement of arterial blood pressure for resting adult, pediatric, and neonatal patients.

Substantial Equivalence – Non-Clinical Evidence:

N/A - E Series ALS is covered under our previously cleared 510(k) submission K111594. This submission is simply intended to seek a stand-alone Class II clearance for E Series ALS, per regulation number 870.5300 for Low-Energy – Defibrillator (LDD), which does not include the Automated External Defibrillators (Non-Wearable) product code (MKJ).

Substantial Equivalence – Clinical Evidence:

N/A - Clinical evidence was not necessary to show substantial equivalence

Comparison of Technological Characteristics

Through a manufacturing configuration option that is already available in the device's software and currently offered for distribution (reviewed and cleared by FDA under K111594), the ECG rhythm analysis (advisory) option can be disabled during the manufacturing of the device. This creates a manual-only/ non-AED configuration of the device which is marketed as E Series ALS and intended to be used by ACLS qualified personnel. E Series ALS does not offer Shock Conversion Estimator (SCE) functionality, which is available in the predicate E Series. On the hardware side, the front panel that is offered with this configuration does not include the analyze button that is used to initiate ECG rhythm analysis.

Performance Testing:

No software modifications were needed to produce the E Series ALS, the manual-only/ non-AED configuration of the device. The capability to configure the device as E Series ALS during the manufacturing process by disabling the ECG rhythm analysis already existed in the predicate device cleared under K111594. No new product or software requirements were introduced in order to produce the E Series ALS configuration of the device, and therefore, no additional design or software verification or validation testing was necessary. This submission is simply intended to seek a stand-alone Class II clearance for E Series ALS, per regulation number 870.5300 for Low-Energy – Defibrillator (LDD), which does not include the Automated External Defibrillators (Non-Wearable) product code (MKJ).

Removal of the "Analyze" button from the front panel of the device did not introduce any new risks, or raise any usability issues or concerns, since users of the E Series ALS configuration of the device are aware that the device does not have ECG rhythm analysis (advisory) and AED functionality. Therefore, additional usability testing was considered unnecessary.

Conclusion

E Series ALS is covered under our previously cleared 510(k) submission K111594. This submission is merely intended to seek a stand-alone Class II clearance for E Series ALS per regulation number 870.5300 for Low-Energy – Defibrillator (LDD), which does not include the Automated External Defibrillators (Non-Wearable) product code (MKJ).